DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-625/S-011
NDA 20-872/S-007

Aventis Pharmaceuticals
399 Interpace Parkway
Parsippany, NJ 07054

Attention: Alan Bergstrom
Senior Manager, U.S. Drug Regulatory Affairs

Dear Mr. Bergstrom:

Please refer to your supplemental new drug applications dated March 1, 2001, received March 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra Capsules (fexofenadine HCl) and Allegra Tablets (fexofenadine HCl).

These "Changes Being Effected" supplemental new drug applications provide for revisions to the ADVERSE REACTIONS section of the package insert.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted March 1, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research